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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,359	10/20/2003	Natarajan Ranganathan	KBI-0015	4537

7590

09/05/2006

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/689,359	Applicant(s) RANGANATHAN, NATARAJAN	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on June 23, 2006 has been received and entered into the case.

Claims 1 – 11 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 – 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halpin-Dohnalek.

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the water activity is less than about 0.47. The probiotic bacteria is selected from a list; the product provides 5 – 20 billion CFUs; the carbohydrate is selected from a list; and the composition further comprises at least one vitamin and mineral.

Halpin-Dohnalek teaches a powdered nutritional composition comprising protein, fat, carbohydrates and the probiotic bacteria *Lactobacillus reuteri*, *L. acidophilis* and

Art Unit: 1651

Bifidobacterium infantis (abstract). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). The compositions further comprise minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). Halpin-Dohnalek provides examples of the composition wherein the compositions provide $10 \times 10^9 - 5 \times 10^9$ (or 5 – 10 billion) CFUs of *L. reuteri* (example 1).

Halpin-Dohnalek does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However the reference does teach that the composition of their mixture may be varied (column 4, lines 1-28) and wherein the composition is a powder (abstract). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

3. Claims 1, 3 – 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jungvid.

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the water activity is less than about 0.47. The carbohydrate, fat, and protein are each selected from a list. The composition further comprises at least one vitamin and mineral. Applicant additionally claims a nutritional food or product for maintaining or enhancing GI health, comprising at least one carbohydrate, fat, protein, vitamin, mineral,

Art Unit: 1651

prebiotic and probiotic, wherein the probiotic has a propensity to hydrolyze nitrogenous waste products and comprising about 2%-12% of at least one fat.

Jungvid teaches powdered nutritional compositions comprising vegetable proteins, whey, vitamins, sodium caseinate, fat (lard, soy oil), animal proteins, starch (a prebiotic), dextrose (carbohydrate), minerals, probiotics (*Lactobacillus bulgaricus*, which hydrolyzes nitrogenous waste products) and lactulose (examples).

Jungvid does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

4. Claims 1, 3 – 5, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul.

Applicant claims to a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient, wherein the composition has a water activity of less than 0.47. The carbohydrate, fat, and protein are each selected from a list. The composition may further comprise at least one prebiotic selected from a list. Applicant finally claims a method for restoring and maintaining gastrointestinal (GI) health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an

Art Unit: 1651

effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity.

Paul teaches compositions for restoring and maintaining GI health, comprising immunogloblins (protein), FOS (prebiotic), pectin (prebiotic), *Lactobacillus* and *Bifidobacteria* (abstract), wherein the compositions are powdered (col.13-14). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the bacteria may be *Lactobacillus acidophilis*, *L. bulgaricus*, *L. casei*, *L. fermentum*, *L. salivaroës*, *L. brevis*, or *L. plantarum*, or *Bifidobacterium adolescentis*, *B. infantis*, *B. longum*, *B. thermophilis*, or *B. bifidum* (col.4 line 20-29). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45).

Although Paul does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Paul does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However, Paul teaches that the composition of the mixture may be varied (column 4, lines 1-52; and column 13, line 47, through column 14, line 38). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the

Art Unit: 1651

invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

5. Claims 1 – 5, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo.

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, about 47%-82% of one carbohydrate, about 2%-12% of one fat, and about 5%-80% of one protein ingredient wherein the composition has a water activity of less than 0.47. The carbohydrate, fat, and protein are each selected from a list. The composition further comprises a prebiotic selected from a list. Applicant further claims a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea-degrading microorganism with pH stability and urea degrading activity; and a yogurt or yogurt based product comprising at least one probiotic, carbohydrate and protein.

Costanzo teaches a yogurt composition (abstract) comprising *Lactobacillus bulgaricus* (probiotic), whole milk (milk proteins), dextrose (carbohydrate) and inulin (a prebiotic) (example 1), with a moisture content of 3 – 8%. Costanzo additionally teaches the yogurts comprising *Lactobacillus bulgaricus*, whole milk (milk proteins), dextrose (carbohydrate), banana smash (prebiotic, or banana fiber), and soy lecithin (fat) (example 2). The compositions may alternatively comprise pectin (prebiotic) (example 3).

Although Costanzo does not specifically teach that the bacteria are ammoniaphilic urea-degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria

Art Unit: 1651

are the same as those claimed. The bacteria of the cited reference must also, intrinsically, have the same characteristics.

Costanzo does not teach the claimed amounts of each component or wherein the water content is less than about 0.47. However, Costanzo teaches that the composition of the mixture may be varied (column 6, lines 50-59, and column 7, lines 20-32). In addition, Costanzo teaches the water level is at 3 – 8%. While this is not the claimed water activity of less than 0.47, it is noted that the specification does teach the water level of less than 5%. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation for successfully obtaining the reference composition. Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

Applicant argues that the references do not teach the claimed water activity and that the water content is not the same as water activity. Applicant attempts to define water activity in the response, in that it refers to unbound water which is important in achieving the desired activity of the composition. Applicant additionally argues that there is no motivation to combine references and that there is no reasonable expectation for success.

However, these arguments fail to persuade because applicant specifically uses the phrases of water content and water activity interchangeably in the specification (p.19). The specification

Art Unit: 1651

identifies water activity and water content on page 19 of the specification and does not define water activity in any other way. While applicant attempts to further define the term in the response, such definition is not permitted and must be made as part of the specification.

Regarding applicant's assertion that there is not a motivation to combine references, it is noted that each of the rejections above are over a single reference, thus motivation to combine appears to be inconsistent with the rejections.

Finally regarding applicant's assertion that there is not a reasonable expectation for success, it is noted that each of the cited references teach the same ingredients combined together for the same purpose. Thus one of ordinary skill in the art would have a reasonable expectation for successfully obtaining an effective nutritional food composition.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1651

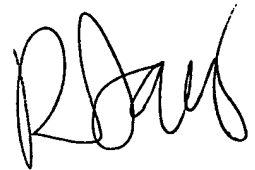
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
Primary Examiner
Art Unit 1651



August 30, 2006